REVISED 510(K) SUMMARY
BIOMONDE LARVAL DEBRIDEMENT THERAPY PRODUCTS – BIOBAG 50/100/200/300/400
(*PER 21CFR 807.92(C)*)

1. SUBMITTER/510(K) HOLDER

BioMonde (*a trading name of ZooBiotic Limited*)
Units 2-4 Dunraven Business Park
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AUG 2 8 2013

Date Prepared: July 23, 2013

2. DEVICE NAME

Proprietary Name: Larval Debridement Therapy Products – BioBag 50/100/200/300/400
Common/Usual Name: Maggots
Classification Name: Unclassified

3. PREDICATE DEVICE

BioMonde Larval Debridement Therapy Products – Larvae 100/200/300 (K123449)

4. DEVICE DESCRIPTION

The BioMonde BioBag 50/100/200/300/400 products are live larvae, stage I and II, of the green bottle fly *Lucilia sericata*, provided within a sterile bag. They are manufactured in five (5) configurations:

- BioBag 50: at least 50 larvae per container
- BioBag 100: at least 100 larvae per container
- BioBag 200: at least 200 larvae per container
- BioBag 300: at least 300 larvae per container
- BioBag 400: at least 400 larvae per container

The larvae are derived from disinfected fly eggs. The BioBags are open mesh polyester bags that come in a variety of sizes based on the dose (number) of larvae to be used. The bags are used to constrain the larvae, preventing them from migrating from the wound. The bags also contain sterile PVA foam cubes that serve as 'spacers' in the BioBags to allow free movement of the larvae within the mesh bag.

Larvae are transferred under controlled manufacturing conditions into sterilized bags after which they are placed into sterile transport tubes which are additionally pouched and boxed for transport. Upon arrival at the treatment location, the BioBags are applied to the wound and covered with permeable and absorbent dressings (not provided).

5. INDICATION FOR USE/INTENDED USE

The BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

Technological characteristics shared by the BioMonde BioBag 50/100/200/300/400 and the parent BioMonde Larvae 100/300/300 are summarized in the Table below.

Side-by-Side Comparison of the Technological Characteristics of the BioBag 50/100/200/300/400 with the Parent Device, Larvae 100/200/300

Technological Characteristics	BioMonde Larval Debridement Therapy Product – BioBag 50/100/200/300/400	BioMonde Larval Debridement Therapy Product K123449
Lucilia sericata/Phaenecia sericata from a closed, monitored colony	Yes	Yes
Oviposition takes place on liver obtained from an approved supplier of animal tissue. Eggs are carefully removed from the liver and weighed.	Yes	Yes
Collected eggs are separated using sodium sulfite solution and mechanical agitation prior to sieving to ensure only single eggs enter the disinfection process.	Yes	Yes
Eggs are disinfected in a two stage process using 7.2% formaldehyde solution and 3.9% peracetic acid solution, after which they are rinsed with sterile sodium chloride 0.9%.	Yes	Yes
Disinfected eggs are inoculated onto the surface of a defined growth medium (Lucilia agar) contained in 90mm petri dishes. The petri dishes are placed into an incubator for 20-24 hours at 31-35°C where the eggs hatch and the larvae reach 2-6mm in size.	Yes	Yes

Technological Characteristics	BioMonde Larval Debridement Therapy Product – BioBag 50/100/200/300/400	BioMonde Larval Debridement Therapy Product K123449
Available in containers of varying numbers of larvae	Yes	Yes
Larvae are removed from the growth medium using a loop or spoon and placed into containers marked with fill heights for the dosage required.		
The correct dosage of larvae is transferred to a sterile transport tube.	No*	Yes
The transport tubes containing the larvae are labeled, the tube is placed into a pouch which is labeled and the pouch is placed into a labeled transport box with the instructions for use.	Yes	Yes

The sole difference between the technological characteristics of the new and cleared product is that larvae are provided within the BioBag rather than as loose larvae. Comparative testing of the two products demonstrates that the application as free larvae as compared to application in constraining netting does not raise new questions of safety and effectiveness.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

This premarket notification presents non clinical testing that includes biocompatibility testing per ISO10993-1 and stability/shelf life testing. In addition, comparative testing that demonstrates that the product fulfills design and performance specifications is also provided. Side-by side-testing of the performance of the BioMonde BioBag, the parent BioMonde Larvae 100/200/300,. and a control demonstrates substantial equivalence in performance. Testing utilized the BioMonde Larval Activity Assay, a method developed and validated by BioMonde to measure the consumption of dead tissue by a certain number of larvae under standardized conditions that are typical of chronic wounds. To mimic clinical conditions, the products were tested after overnight delivery to the test location. Samples of free range Larvae300 (parent device), the BioBag100 (modified device), and empty bags (identical to the BioBag product but without larvae) were tested in triplicate. The first acceptance criterion for this study was that clearly observable differences between the wet and dry mass consumed (in grams) for the loose and bagged larvae test samples were required when compared to a control group of BioBags with no larvae. The second acceptance criterion for this study was that both the BioBag and loose larvae product consume at least 30g of tissue over the course of the 48 hour experiment per Blake et al., 2007 who showed that a single maggot was capable of debriding approximately 0.15g of dead tissue per day in a wound model (equating to 30g over a 2 day period).

Testing was performed in compliance with prospectively defined procedures. Analysis of the mean values of both dry and wet mass consumed show that the average mass consumed per 100 larvae for both loose and BioBag larvae product configurations is much greater than that of the control group and the results for the bagged larvae are much closer to that of the loose larvae than the control. The second acceptance criterion was met by both the loose and the BioBag product configurations (46.11 and 36.01g respectively) with the dry weight target being 5.53g, again achieved by both loose and bagged larvae (12.38 and 7.89g respectively).

Based on the results, BioMonde concluded that while there is a difference in the overall consumption by loose larvae (cleared product) and BioBag configurations (modified product) under the conditions of this test, the difference does not raise new issues of safety or effectiveness. This difference in overall performance is covered by the labelling (instructions for use) for the product.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical data were included in this 510(k) Premarket Notification.

9. Summary of Other Information

Other information provided in the 510(k) included manufacturing information and information from the scientific literature.

10. Conclusions Drawn From Non-clinical and Clinical Tests

Based on the information provided in this 510(k) Premarket Notification, BioMonde has determined that the BioMonde BioBag 50/100/200/300/400 and the parent BioMonde Larvae 100/300/300 are substantially equivalent, that differences are minor, and do not raise new safety and effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 28, 2013

BioMonde
% Aptiv Solutions
Rosina Robinson, RN, MED, RAC
62 Forest Street, Suite 300
Marlborough, Massachusetts 01752

Re: K131221
Trade/Device Name: BioMonde Larval Debridement Therapy Products – BioBag 50/100/200/300/400
Regulatory Class: Unclassified
Product Code: NQK
Dated: July 23, 2013
Received: July 24, 2013

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rümm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K131221

Device Name: BioMonde Larval Debridement Therapy Products – BioBag 50/100/200/300/400

Indications for Use:

The BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131221